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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,939	11/04/2003	Guohua Chen	ARC 3307 US R1	5013

7590 03/23/2007
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EXAMINER

KENNEDY, SHARON E

ART UNIT	PAPER NUMBER
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1615

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/701,939	Applicant(s) CHEN ET AL.	
	Examiner Sharon E. Kennedy	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/21/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-113 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5, 29, 30, 52, 53, 72-79, 82, 83, 106-113 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-71 and 80-105 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :09/27/2004;05/03/2004; 04/12/2004.

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I and Species I in the reply filed on December 21, 2006 is acknowledged.

Claims 4, 5, 29, 30, 52, 53, 72-79, 82, 83, 106-113 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-71 and 80-105 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-46 of

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compending Application No. 10/985,116. Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims are directed to an injectable depot composition in a gel form and having the solvent with the specific miscibility characteristics and the particular bioerodible polymer. The claims of the '116 application are broader than the instant claims, however, the examiner notes claims 14, etc., directed to the solvent having the specific miscibility.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-71 and 80-105 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-46 of compending Application No. 10/985,122. Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims are directed to an injectable depot composition in a gel form and having the solvent with the specific miscibility characteristics and the particular bioerodible polymer. The claims of the '122 application are broader than the instant claims, however, the examiner notes claims 14, etc., directed to the solvent having the specific miscibility.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-71 and 80-105 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-57, 115, 116, filed December 9, 2005, of compending Application No. 10/295,814. Although the conflicting claims are not identical, they are not patentably distinct from each other

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because each set of claims are directed to an injectable depot composition in a gel form and having the solvent with the specific miscibility characteristics and the particular bioerodible polymer. It is noted that the '814 application's claims further require a thixotropic agent, however, the claims of this application encompass those claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-71 and 80-105 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-55, filed October 27, 2006, of copending Application No. 10/628,984. Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims are directed to an injectable depot composition in a gel form and having the solvent with the specific miscibility characteristics and the particular bioerodible polymer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-71 and 80-105 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-60, filed October 13, 2006, of copending Application No. 10/606,969. Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims are directed to an injectable depot composition in a gel form and having the solvent with the specific miscibility characteristics and the particular bioerodible polymer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-71 and 80-105 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21, 23-52, 54-87, 110-112, filed November 24, 2006, of copending Application No. 10/295,603.

Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims are directed to an injectable depot composition in a gel form and having the solvent with the specific miscibility characteristics and the particular bioerodible polymer. It is noted that the '603 application's claims further require a thixotropic agent and a catheter injectable depot, however, the claims of this application encompass those claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-71 and 80-105 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 6-48, 98-104, filed August 14, 2006, 2005, of copending Application No. 10/295,527. Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims are directed to an injectable depot composition in a gel form and having the solvent with the specific miscibility characteristics and the particular bioerodible polymer. It is noted that some of the '527 application's claims further require a thixotropic agent, however, the claims of this application encompass those claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is becoming common to delay filing the terminal disclaimer(s) until all the claims are indicated as allowable. However, this places a burden on the examiner and the USPTO to conduct additional paper processing, docketing, and examination. Accordingly, applicant must file the terminal disclaimer(s) in response to this office action or supply substantive arguments against the double patenting rejection(s). Any response that attempts to delay these issues will be held non-responsive. In addition, it is noted that some of the claims of the related applications are withdrawn, however, until these claims are cancelled, the double patenting rejections must be applied.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-9, 14-19, 21-28, 31-34, 39-44, 46-51, 54-57, 62-67, 69-71, 80, 81, 84-87, 92-97, 99-105 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dunn et al., WO 02/38185. Note the polymers set forth in page 4, lines 1-21, and the solvents listed thereafter. Note especially the disclosure of benzyl benzoate and benzyl alcohol as solvents on page 5, line 1. Poly(dl-lactide-co-glycolide) is disclosed on page

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4, line 17. Regarding the claim language "viscous," Dunn discloses various molecular weights. In the absence of any quantitative definition of "viscous" in the claims, Dunn anticipates this embodiment. Regarding claim 6, see Dunn Examples 1 or 2 on page 21. Regarding the time frame, Dunn discloses the composition can be delivered once every 30 days. See page 6, line 20. Regarding the limitation requiring the delivery to be provided at multiple sites, the examiner takes that position that this is inherent from the Dunn disclosure. This claim merely recites a common medical practice decision made routinely by a doctor during the ordinary course of a working day.

Claims 1-3, 6-28, 31-51, 54-71, 80, 81, 84-105 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Brodbeck et al., US 6,130,200. The identical gel composition is already disclosed in applicant's previous patent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10-13, 15, 20, 35-38, 40, 45, 58-61, 63, 68, 88-91, 93 and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al., '185. Regarding claims 10-13, 35-38, 58-61 and 88-91, Dunn discloses a time period of preferably 3 to 30 days. However, Dunn discloses that changing various embodiments of the composition affect the delivery period, including the amount of composition injected into the patient (page 19, lines 30-35). Further, it is well known in the art that increasing the total amount of drug in a delivery vehicle will prolong the delivery rate, or increasing the molecular weight of the polymers, increasing the size of the implant, etc. These are rudimentary, predictable considerations. Accordingly, it would be obvious to one of ordinary skill in the art to modify the Dunn composition, by increasing overall injection volume, increasing the amount of drug injected, modifying the molecular weights of the polymers, etc., to extend the life of an injectable composition for the obvious benefit of preventing patient discomfort via fewer needle sticks. Regarding claims 15, 40, 63 and 93, Dunn discloses that the composition may be used to form a gelatinous microporous matrix. It would be obvious to add a pore former to further ensure the formation of the microporous matrix if necessary. Regarding claims 20, 45, 68 and 98 directed to the ethyl benzoate solvent, Dunn already discloses the solvent is to be dispersible or miscible in an aqueous medium, but does not list this specific solvent. However, in view that ethyl benzoate and benzyl benzoate are similar solvents with almost identical

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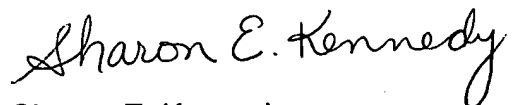
properties, it would be obvious to one of ordinary skill in the art to use either in the lack of a showing of criticality.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sharon E. Kennedy
Primary Examiner
Art Unit 1615